

Application No. 09/815,646  
Art Unit 3626

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Remarks

Claims 8, 10 -15 and 19-22 are pending in the application. Claim 8 is amended. Claims 19-26 are new. Claims 1-7, 9, and 16-18 are canceled. Claims 10 - 15 are withdrawn from consideration due to election/restriction.

Claim Rejections 35 USC §103

**Claims 1 and 3 - 7: Lee et al. (5828776)**

Claims 1 and 3 - 7 have been rejected under 35 USC § 103 as being unpatentable over Lee et al. ("Lee") (5828776). Applicant respectfully traverses this rejection.

Claims 1 and 3-7 are cancelled, herein. Accordingly, Applicant respectfully requests removal of this rejection.

**Claims 17 and 18: Lee and Anderson (6267722)**

Claims 17 and 18 have been rejected under 35 USC § 103 as being unpatentable over Lee in view of Anderson (6267722). Applicant respectfully traverses this rejection.

Claims 17 and 18 are cancelled, herein. Accordingly, Applicant respectfully requests removal of this rejection.

**Claim 2: Lee et al. (5828776) and Friedman (6055494)**

Claim 2 has been rejected under 35 USC § 103 as being unpatentable over Lee et al. (5828776) as applied to claim 1 and further in view of Friedman (6055494). Applicant respectfully traverses this rejection.

Claim 2 is cancelled, herein. Accordingly, Applicant respectfully requests removal of this rejection.

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**Claim Rejections 35 USC §102**

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**Claims 8, 9 and 16: Lapointe et al. (2003:0105731)**

Claims 8, 9 and 16 have been rejected under 35 USC §102(e) as being anticipated by Lapointe et al. US Patent Publication 2003/0105731. Applicant respectfully traverses this rejection.

Examiner cites Lapointe et al. Fig. 11A, page 19, paragraphs 0311-0313 as support for generating an overall level of confidence parameter according to Applicant's claim 8. In particular the Examiner contends, "the medical conclusion(s) in this clinical application are. A low, high or moderate risk of preterm delivery within a time frame, and the calculated risk value for the associated interpretations (i.e. low, high or moderate) representing the confidence parameter of the conclusion(s)" See Office Action mailed on 1/9/2007, page 7, paragraph f.

The risk index and risk assessment and risk interpretation are different than the overall confidence parameter of claim 8. For example, Lapointe et al. uses a risk index to lead to an interpretation which the Examiner contends is a confidence parameter of a conclusion. In Lapointe et al. paragraphs 0311-0313, the risk index is just an index defining thresholds for interpretation of low, moderate or high risk. The thresholds are predetermined prior to making an interpretation of risk, or even performing patient symptom or data analysis.

Applicant's claim 8 recites, "generating an overall confidence parameter for the medical ~~clinical conclusion as a ratio of a first product of the first impact parameter and the first~~ confidence parameter to a second product of the second impact parameter and the second confidence parameter." This represents a product and ratio calculation that yields an overall level of confidence parameter for a medical clinical conclusion and is very different than a threshold or index. For example, using the index involves a one to one comparison and does not

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disclose performing any type of product or ratio analysis between data sets such as confidence parameters and impact parameters. Additionally, the indices of Lapointe are fixed, predetermined numbers for each conclusion while the overall level of confidence parameter as recited in claim 8 varies based on the selected medical conclusion, impact parameters and confidence parameters.

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Accordingly, Lapointe fails to disclose the features of claims 8. Claims 9 and 16 are canceled, herein. Therefore, Applicant respectfully requests reconsideration and withdrawal of this rejection and allowance of claim 8.

#### New Claims

Claims 19-22 newly added and contain allowable subject matter. These claims are supported by the Specification by at least Figures 8a, 8b, 9a and 9b and paragraphs 0071-0084.

Lee et al. (5828776) fails to teach, disclose or make obvious to one of ordinary skill in the art the feature of determining an overall level of confidence, as recited by claim 19. Lee et al. pertains to a method and apparatus for tissue and/or cell classification such as a Pap smear. This classification is performed using a predetermined threshold. The classification data is then used to merely to determine an "overall rating" and conclusion regarding the condition of the tissue sample of a slide. According to Lee et al. column 18, lines 58-65, "The overall rating is then compared to a predetermined normal value PNV and, if the overall rating is less than the predetermined normal value (PNV), then the slide is identified as normal, step 1620. If, however, the overall rating N is greater than or equal to the predetermined normal value, then the slide is identified as a slide needing further investigation, step 1622, and must be reviewed by a cytotech."

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New independent claim 19 recites, "determining the overall level of confidence for the selected medical conclusion as a ratio of the first conclusion value and the second conclusion value." Thus, at least the feature of the overall level of confidence as recited in claim 19 is not taught by Lee et al., which merely appears to discuss a "a greater than or equal to" function.

Further, Lee et al. teaches against the need for any type of evaluation of the accuracy or overall confidence of its conclusion. In Column 20, lines 1-3, Lee et al. states, "PNV, may be selected wherein the relative magnitude of the normal value will determine in part, the accuracy of the method." Thus, Lee et al. suggests a method to control the accuracy of its conclusion. For example, prior to analyzing a tissue sample, the PNV could be increased or decreased to change the accuracy of the conclusion regarding normalcy.

This attribute of Lee et al. allows a user to knowingly predict the accuracy of the tissue analysis before he or she performs the analysis. Therefore, the user knows the accuracy of the analysis before the test is performed. At least for this reason, Lee et al. does not render it obvious to one of ordinary skill in the art to perform any other analysis or evaluation of the confidence or accuracy of the tissue sample results.

As discussed above, Lapointe et al. appears to disclose interpreting risk based on comparison to predetermined indices. This also does not disclose at least, "determining the overall level of confidence for the selected medical conclusion as a ratio of the first conclusion value and the second conclusion value," as recited by claim 19.

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Claims 20-22 are dependent from claim 19. These claims contain allowable subject matter at least by virtue of their dependence on claim 19.

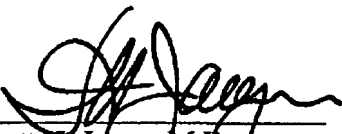
### Conclusion

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In view of the above discussions, it is respectfully submitted that each of claims 8 and 19 - 22 contain allowable subject matter. A notice of allowance to this effect is requested. In the alternative, continued prosecution is requested.

Thank you very much for considering the above comments. Any assistance that you can provide in the prosecution of my patent application is greatly appreciated. If you have any questions or need any further assistance or clarification, please do not hesitate to contact the undersigned at (856)313-6630 or (215)629-1045.

  
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Scott H. Jaeger M.D.  
Applicant/Inventor